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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/699,921

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Dennis M. Treu

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PATENT DEPARTMENT
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EXAMINER

WIEST, PHILIP R

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

05/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/699,921

Applicant(s)

TREU, DENNIS M.

Examiner

Phil Wiest

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3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-8 and 11-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8 and 11-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

In the response filed 3/13/07, applicant canceled claims 5, 9, and 10, amended claim 6, and added new claims 11-18.

Claim Objections

Claim 17 is objected to because of the following informalities: Claim 17 depends from Claim 9, which has been canceled. For the purposes of examination, the examiner has treated Claim 17 as being dependant from Claim 6. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim does not distinctly disclose what the separate components are connected to by way of the one-way communication channel. For the purposes of examination, based on applicant's specification and Figure 1, the examiner has interpreted this to mean that the control panel is in one-way communication *with the monitoring device*.

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 3, 6, 8, and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Causey, III et al. (US 6,641,533)
3. With respect to Claim 1, Causey, III et al. disclose a medical treatment device that can be connected to a computer (monitor unit) 6, the system comprising a treatment unit 400, a monitor unit 6, said treatment unit 400 comprising an infusion pump that delivers a medical treatment to a patient. The monitor unit 6 is capable of receiving data from the treatment unit 400 via a common control unit (200, 300) (Column 23, Lines 49-52) and outputting at least data relating to the status of the treatment being delivered on a display portion 12. Regarding the one-way transmission of data, Causey, III et al. further discloses that the computer 6 (monitoring portion) is capable of receiving data from the treatment unit 400 via a medical device module 200 for analysis (Column 23, Lines 49-52 and Figure 10), but does not disclose the computer 6 transmits data back to the medical device module 200 (as demonstrated by the one-way arrow to the communication station in Figure 10). Therefore, Causey, III et al. discloses a one-way communication channel between the treatment unit (400 by way of 200) and the monitoring device 6, such that the treatment machine 400 is not affected by a data-processing software being operated by the monitor device 6.
4. With respect to Claim 3, Causey, III et al. disclose that the treatment unit 400 and monitor unit 6 are connected to a common control unit (200, 300) (see Figures 7 and

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10). The common control panel (200, 300) is capable of controlling and receiving data from the treatment unit 400, as well as transferring said data to the monitoring unit 6. Because the monitoring unit 6 does not transmit data back to the common control unit (200, 300), as shown by the one-way arrow in Figure 10, any signals from the monitor unit 400 are prevented from affecting a state of the treatment unit 400.

5. With respect to Claim 16, Causey III, et al. discloses that the computer 6 provides at least one enhanced information (data processing, calibration, etc). Because applicant does not does not define or limit what is meant by “providing at least one enhanced information” entails, said enhanced information may be any form of information not processed by the treatment machine. The computer of Causey, III et al. is capable of downloading the stored information for evaluation, analysis, calibration, or the like (Column 14, Lines 45-51).

6. With respect to Claim 6, Causey, III et al. disclose a medical treatment device that can be connected to a computer 6, the system comprising a treatment machine (200, 400) and monitor device 6 (see Figures 7 and 10), having a programmable processor and a memory, where the processor is capable of being programmed to control data synthesis and display responsive to software run by the programmable processor (Column 23, Lines 49-52). Regarding the one-way transmission of data, Causey, III et al. further discloses that the computer 6 (monitoring portion) is capable of receiving data from the medical device module 200 for analysis (Column 23, Lines 49-52 and Figure 10), but does not disclose the computer 6 transmits data back to the

medical device module 200 (as demonstrated by the one-way arrow to the communication station in Figure 10). Therefore, Causey, III et al. discloses a one-way communication channel between the treatment machine (200, 400) and the monitoring device 6, such that the treatment machine 400 is not affected by a data-processing software being operated by the monitor device 6, and therefore is capable of operating without said monitoring device.

7. With respect to Claim 8, Causey, III et al. disclose that the communications channel between the may be wireless (Column 24, Lines 4-15).

8. With respect to Claim 17, Causey III, et al. discloses that the computer 6 provides at least one enhanced information (data processing, calibration, etc). Because applicant does not does not define or limit what is meant by "providing at least one enhanced information" entails, said enhanced information may be any form of information not processed by the treatment machine. The computer of Causey, III et al. is capable of downloading the stored information for evaluation, analysis, calibration, or the like (Column 14, Lines 45-51).

9. With respect to Claim 15, Causey, III et al. discloses a medical treatment device 400 comprising a medical treatment unit with a patient interface, status indicators 2208, and operator controls 2202 that delivers a treatment to a patient. The device further comprises a status device 6 (previously referred to as the monitoring device or computer 6) with operator controls (input device) and status indicators (via the monitor screen) configured to receive status information via a one-way data connecting the

treatment device to the status device. The treatment unit and status device are separate computers that communicate with one another through a one-way data channel (figure 29), whereby any changes in the programming of the status device (computer 6) will not affect the operation of the medical treatment unit. The status device (computer 6) provides at least one enhanced information (data processing, calibration, etc). Because applicant does not does not define or limit what is meant by "providing at least one enhanced information" entails, said enhanced information may be any form of information not processed by the treatment machine. The computer of Causey, III et al. is capable of downloading the stored information for evaluation, analysis, calibration, or the like (Column 14, Lines 45-51). Furthermore, the treatment unit and status device are fully capable of being located together (i.e. "co-located") in a fixed relationship at a position adjacent a treatment location

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 2, 4, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Causey, III et al. in view of Gilcher et al. (US 6,113,554). Causey, III et al. teach the medical treatment devices as disclosed in Claims 1 and 6, but do not teach that the treatment unit and monitor unit are housed together in a single housing. Gilcher et al. disclose a blood collection system comprising a housing 14 that houses a monitor unit 10 and a treatment unit 12. The housing further comprises a control panel 72, as per

Claim 4. It would have been obvious to one skilled in the art at the time of medical treatment device of Causey, III et al. with the unitary housing of Gilcher et al. in order to provide a simplified unit for medical treatment that does not comprise several parts. Furthermore, Causey et al. disclose that the device was broken into components in order to improve price and upgradability, and that some devices would preferably be combined into a single device. The components that comprise the medical treatment device are more than capable of functioning as a singular unit in a common housing.

11. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Causey, III et al. Causey, III et al. discloses a medical treatment device comprising treatment and monitoring devices with separate control systems for treatment (via the treatment device) and pure monitoring (via the computer) functions. The treatment unit comprises components 400 that deliver medical treatment to a patient including a control panel 2202 that is physically separate from the computer 6 (see Figures 29 and 33). The computer 6 is signally connected to the treatment unit by means of a one-way communication channel such that said computer 6 is prevented from affecting the state of the treatment unit (see the one-way arrow in Figure 29). The computer receives data from the treatment unit and outputs data relating to the status of the treatment of the treatment being delivered by the treatment unit (Column 14, Lines 45-51). Regarding Claim 13, the control panel comprises components that are physically separate from the monitor device (computer 6) and connected to by a one-way communication channel. The monitoring unit and treatment unit are signally isolated from each other except for

the one-way communication channel (see Figure 29), as per Claim 14. Causey, III et al., however, does not disclose that the treatment and monitoring devices are in a unitary housing. However, the use of an integral housing would be an obvious variation on the device of Causey, III et al. and, because the components communicate wirelessly, has no functional advantages over separated components. See MPEP 2144.04. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the monitor device and treatment device into a single housing because doing so does not give additional functionality over the device of Causey, III et al.

Response to Arguments

12. Applicant's arguments filed 3/13/07 have been fully considered but they are not persuasive.

Regarding Claim 1, applicant argues that Causey, III et al. does not disclose a computer that is positioned together at a treatment location. The examiner interprets this to be different than the "unitary" device of applicant's newly added claims. The computer is fully capable of being positioned in any manner, because the system is wireless, the exact position of the computer is irrelevant. The computer of Causey, III et al. has the same functionality as claimed by applicant. Additionally, applicant argues that the medical device module 200 is not a "treatment unit including components that deliver medical treatment to a patient." As stated in the prior office action, the

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"treatment unit" is identified by numeral 400, which corresponds to an infusion pump.

The infusion pump delivers a medical treatment to a patient.

13. Regarding Claim 6, applicant argues that Causey, III et al. does not disclose that the monitor device does not provide at least one enhanced information not provided by the treatment machine. Because applicant does not does not define or limit what is meant by "providing at least one enhanced information" entails, said enhanced information may be any form of information not processed by the treatment machine. The computer of Causey, III et al. is capable of downloading the stored information for evaluation, analysis, calibration, or the like (Column 14, Lines 45-51). Because this analysis is performed specifically on the computer and not the treatment device, this and all other limitations of Claim 6 are met.

14. Regarding Claims 2, 4, and 7, applicant argues that there is no motivation to combine the Causey, III et al. and Gilcher et al. references because support for the rejection of the base claims is absent. However, for the reasons discussed above, the base claims are supported by Causey, III et al.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW
5/21/07

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

